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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/235,416	01/22/1999	ROMAN SAKOWICZ	UCSD-04742	4745

23535 7590 10/23/2006

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/235,416	SAKOWICZ ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33 and 47-101* is/are pending in the application.

4a) Of the above claim(s) *1-33,47-87 and 97-101* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *88-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/7/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group IV in the reply filed on October 9, 2003 is acknowledged. The traversal is on the ground(s) that the claims are not distinct one from another; the classification is wrong; and there are not different fields of search.

This argument is not found persuasive because the inventions are distinct and unrelated, each from the other because of the reasons previously provided. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The methods are distinct as claimed because each group requires the use of a different reagent, wherein the different reagent are defined as: TL-gamma, TL-gamma with 60% identity to SEQ ID NO:1, a tail domain with 60% identity to amino acids 602-784 and a tail domain with 60% identity to amino acids 1-357. Because each group requires a different reagent, the method of screening associated with the reagent will cause a different mode of operation. Furthermore, each group is drawn to a separate and distinct sequence. The inventions are distinct, each from the other because of the following reasons: Although there are no provisions under the section for "Related Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different products used within a variety of methods; restriction is deemed to be proper because these products appear to constitute patentably distinct inventions. These TL-gamma, products appear to constitute patentably distinct inventions for the following reasons: the groups use different sequences which are distinct physically,

structurally, and functionally and are therefore patentably distinct, each group from the other, and one sequence is not required to practice the other. Each group comprises separate and distinct amino acid sequences that do not share a substantial structural feature disclosed as being essential to the utility of the invention. Therefore, for these reasons the inventions are patentably distinct.

Contrary to applicants' arguments drawn to the classification being wrong, it is noted that the class and subclass chosen are not wrong. The methods are drawn to identifying modulators, however it is extremely possible that the modulators are enzymes. Thus classifying the method in a subclass which determines the identity of enzymes is not wrong as applicants urge. Furthermore, the classification system is not the only criteria for determining the distinctness of the groups. Therefore, applicants' arguments are not persuasive.

Applicants' argue that there would be no serious burden on the Examiner to search for the other groups because of the field of search. However, in the instant case these inventions are unrelated and distinct. The methods are distinct as claimed because they are drawn to measuring or performing different activities. Furthermore the distinct products require separate and distinct searches. For instance, a search for a sequence that shares at least 60% sequence identity to a sequence comprising amino acids 1 to 357 of SEQ ID NO:1, would not encompass sequences comprising the tail domain that shares 60% identity with amino acids 602 through 784 of SEQ ID NO:1. As such, it would be burdensome to search the inventions of groups together. Furthermore, a search for the invention of the groups would not be coextensive because a search

indicating the process of one is novel or unobvious would not extend to a holding that the other is novel or unobvious. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden on the examination of this application.

Applicants' argument that the groups are not distinct is not found persuasive because contrary to applicants arguments the inventions have been shown to be distinct in view of: the different methods that require different components; the production of different effects; and the different capabilities of those functions as compared to the other groups.

Furthermore, applicants state that the claims should be rejoined. However the examiner has not required restriction between product and process claims. Therefore there is no case where applicants elect claims directed to the product, and a product claim is subsequently found allowable, thereby causing the withdrawal of the process claims that depend from or otherwise include all the limitations of the allowable product claim. Therefore this argument is not persuasive. The requirement is still deemed proper and is therefore made FINAL.

Claim Status

2. Claims 59-101 have been added. However it is noted that claims 97-101 should be grouped with Group I, as the claims are drawn to biologically active TL-gamma, thus, claims 97-101 are withdrawn. Claims 1-33, 47-87 and 97-101 are withdrawn from

consideration as being directed to non-elected inventions. Claims 34-46 have been cancelled. Claims 88-96 are under consideration in this office action.

Information Disclosure Statement

3. The information disclosure statement filed May 7, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The disclosure is objected to because of the following informalities: The attempt to incorporate subject matter into this application by reference to http://www. ncbi. nlm. nih. gov/ is improper because Applicants have embedded a hyperlink which is impermissible and requires deletion. This attempt to incorporate subject matter into the patent by reference is improper because PTO policy does not permit the PTO to link to any commercial sites since the PTO exercises no control over those organizations,

views or accuracy of the information contained on those outside sites. Appropriate correction is required.

Withdrawal of Rejections

5. The following rejection have been withdrawn in view of applicants amendments:

a) The rejection of claims 34-46 under 35 U.S.C. 112, second paragraph;

b) The rejection of claims 34,36-39 and 41 under 35 U.S.C. 102(a) as being anticipated by Au-Young;

c) The rejection of claims 34-41 under 35 U.S.C. 103(a) as being unpatentable over Au-Young in view of Foulkes; and

d) The rejection of claims 34-39, 41 and 43-46 under 35 U.S.C. 103(a) as being unpatentable over Au-Young.

Response to Arguments

6. Applicant's arguments with respect to claims 34-46 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 88-96 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to a method of screening for modulators of TL-γ, comprising in operable order the steps of: a) providing: (i) biologically active TL-γ, wherein the biological activity of said TL-γ, is selected from the group consisting of plus end-directed microtubule motor activity, binding activity, and ATPase activity, and wherein said biologically active TL-γ, comprises a motor domain wherein said motor domain sequence shares at least 60% sequence identity with the sequence comprising amino acids 1through 357 of SEQ ID NO:1, (ii) a candidate agent, wherein said candidate agent is provided in a test concentration and a control concentration, and (iii) a testing assay; (b) contacting said biologically active TL-γ, with said test concentration of said candidate agent in said testing assay to produce a test mixture; (c) contacting said biologically active TL-γ, with said control concentration of said candidate agent in said testing assay to produce a control mixture; (d) assaying the level of TL-γ, activity in said test mixture; (e) assaying the level of TL-γ, activity in said control mixture; (f) comparing the TL-γ activity in said test mixture and said control mixture, wherein difference in the TL-γ activity in said test mixture and said control mixture indicate that said candidate agent is a modulator of TL-γ.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.*, the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it

from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. *In Gostelli*, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872 F.2d at 1012, 10 USPQ2d at 1618.

The claims are drawn to a biologically active TL-γ, comprises a motor domain wherein said motor domain sequence shares at least 60% sequence identity with the sequence comprising amino acids 1 through 357 of SEQ ID NO:1, however this lacks the necessary written description. The written description in this case sets forth the specifically recited amino acids of SEQ ID NO:1, therefore the written description is not commensurate in scope with the claims drawn to sequences having greater than 60% sequence identity. The specification does not include structural examples of the sequence having greater than 60% sequence identity to amino acids 1 to 357 of SEQ ID

NO:1. Furthermore, the specification lacks a sufficient number of representatives, which the Courts have indicated as necessary to adequately describe broad generic claims. There is no guidance as to what regions may be added, deleted or subjected within amino acids 1 to 357. Thus the skilled artisan cannot envision the detailed chemical structure of the encompassed sequences having greater than 60% sequence identity to amino acids 1 to 357 of SEQ ID NO:1.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

With the exception of specifically named amino acids 1 to 357 of SEQ ID NO:1, the skilled artisan cannot envision the detailed structure of the parts of these sequences, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. Furthermore, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the

scope of the claimed genus. Therefore the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph.

8. Claims 88-96 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for a method of screening for modulators of TL-γ, comprising providing a biologically active TL-γ, wherein the biological activity of said TL-γ, is selected from the group consisting of plus end-directed microtubule motor activity, binding activity, and ATPase activity, and wherein said biologically active TL-γ, comprises a motor domain wherein said motor domain sequence shares at least 60% sequence identity with the sequence comprising amino acids 1 through 357 of SEQ ID NO:1, as recited by the claims.

Applicant did not point to support in the specification for a biologically active TL-γ, comprises a motor domain wherein said motor domain sequence shares at least 60% sequence identity with the sequence comprising amino acids 1 through 357 of SEQ ID NO:1 used in a method of screening for modulators of TL-γ. Moreover, applicant failed to specifically point to the identity or provide structural characteristics of biologically active TL-γ, comprises a motor domain wherein said motor domain sequence shares at

least 60% sequence identity with the sequence comprising amino acids 1through 357 of SEQ ID NO:1. Thus, there appears to be no teaching of any biologically active TL-γ, comprises a motor domain wherein said motor domain sequence shares at least 60% sequence identity with the sequence comprising amino acids 1 through 357 of SEQ ID NO:1. Applicant has pointed to pages 5-10 of the instant specification and claims for support of the amendment which are drawn a biologically active TL-γ, comprises a motor domain wherein said motor domain sequence shares at least 60% sequence identity with the sequence comprising amino acids 1 through 357 of SEQ ID NO:1 used in a method of screening for modulators of TL-γ. However it appears that the entire specification appears to fail to recite support for the newly recited amendment. Those pages teach the method without using a biologically active TL-γ, comprises a motor domain wherein said motor domain sequence shares at least 60% sequence identity with the sequence comprising amino acids 1 through 357 of SEQ ID NO:1. There are no representative examples of any biologically active TL-γ, comprises a motor domain wherein said motor domain sequence shares at least 60% sequence identity with the sequence comprising amino acids 1 through 357 of SEQ ID NO:1 used in a method of screening for modulators of TL-γ. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for the identity of the instantly recited method. Thus, the new claims incorporate new matter and are accordingly rejected.

9. Claims 88-96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Acronyms like TL-γ in claim 88, must be spelled out when used for the first time in a chain of claims.

b) Claim 88 is unclear. It is unclear if assaying for "TL-γ activity" is equivalent to assaying for the biological activity of TL-γ or if a different activity is measured assayed. Therefore, clarification is required to overcome this rejection.

c) Claims 93 and 96 are vague and indefinite. The term "has identity to" in the claims is a relative term which renders the claim indefinite. The term is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. If is unclear what the metes and bounds are for determining identity. Therefore, clarification is required to overcome this rejection.

Conclusion

10. No claims allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, A. Mark Navarro can be reached on 571-272-0861. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
October 11, 2006

MARK NAVARRO
PRIMARY EXAMINER